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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,804	07/23/2003	Subhashis Banerjee	BBC-156	9032

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,804	BANERJEE, SUBHASHIS	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *8-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed 6/19/06 is acknowledged and has been entered.

2. Applicant's election with traverse of Group I (claims 1-7), a method for detecting a deantigenized Class I MHC T cell epitope, and species of dissociation constant of about 5×10^{-3} M for the binding of the deantigenized T cell epitope to soluble MHC molecule in Applicant's said response filed 6/19/06 is acknowledged.

Applicant's traversal is of record on pages 5-7 of Applicant's said response, briefly that: (1) the invention must be independent and distinct, (2) and there must be a serious burden placed on the Examiner by not requiring election, (3) the claims are drawn to a single inventive concept and the entire application can be searched and examined without serious burden, (4) the method for detecting a deantigenized T cell epitope, the said epitope, and method of using the said epitope to diagnose, prevent or treat a disease are all linked, and are therefore not "independent," (5) separate field of search means it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, (6) searches with regard to inventions in the same class and subclass would be co-extensive and would not involve a serious burden on the Examiner, (7) a search of groups I and II with regard to all MHC molecules could not place a serious burden on the Examiner, and (8) the product of groups III-VIII can only be generated by practicing the method of group I.

Applicant's arguments have been fully considered, but are not persuasive.

It is the Examiner's position that: There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent (see MPEP 802.01, 806.04, 808.01) ***OR*** *(not "and" as asserted by Applicant)* distinct as claimed (see MPEP 806.05 - 806.05(I)); (with respect to Applicant's arguments "(1)" and "(4)" above, and

(2) There must be a serious burden on the Examiner if restriction is not required (see MPEP 803.02 806.04(a) - (j), 808.01(a) and 808.02). Regarding undue burden, the M.P.E.P. 803 (July 1998) states that: "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search".

The inventions are ***distinct*** for reasons elaborated in paragraphs 2-9 of the previous Office Action. With regard to Applicant's argument "(8)," the deantigenized T cell epitope of groups II-VIII can be made by a different method wherein the detecting step utilizes binding to a cell surface MHC molecule rather than to a soluble MHC molecule as recited in instant base claim 1 of group I, and optionally wherein the recognition of said altered T cell epitope is further detected by contacting a CTL specific for the MHC/unaltered T cell epitope peptide with the MHC/altered T cell epitope peptide.

With regard to Applicant's arguments "(2)", "(3)", "(5)", "(6)" and "(7)"above, the following applies. Where the related inventions as claimed are shown to be independent or distinct under the criteria of MPEP 806.05(c)-806.06, the Examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the Examiner if restriction is not required. Thus the Examiner must show by appropriate explanation one of the following:

A. Separate classification thereof: This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

B. A separate status in the art when they are classifiable together: Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the Examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents that are evidence of such separate status, and also of a separate field of search.

C. A different field of search: Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other inventions (*e.g.,* searching different classes/subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classifiable together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

The restriction requirement enunciated in the previous Office Action meets this criterion of serious burden and therefore establishes that serious burden is placed on the Examiner by the examination of additional groups, and with regard to "(3)" in addition, the restriction requirement is made under 35 U.S.C. 121, not under 35 U.S.C. 372, and so an argument to the groups of inventions being linked so as to form a single inventive concept is off point. With regard to Applicant's arguments "(5)" -"(7)" above, the said restriction requirement demonstrates searching either different classes/subclasses or employing different search queries if the two are classifiable together: for example, in Group I, searching for a CTL epitope of 8-11 amino acid residues with a binding motif for an MHC class I molecule that stimulates a CTL response, whereas in Group II, searching for a Th epitope of unspecified length with a motif for binding an MHC class II

molecule and stimulating a Th cell response or for example, in Groups III-VIIII, searching for different polypeptides of different structure and biological function for candidate T cell epitopes that may be altered without affecting the biological function of the said polypeptides. In addition, a search of "antibody," for example, would not necessarily reveal art on an enzyme, adjuvant, carrier, receptor or ligand.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2 and 5-7 read upon the elected species.

Upon consideration of the prior art, the search has been extended to include the species of dissociation constant recited in instant claims 3 and 4.

Accordingly, claims 8-20 (non-elected groups II-LXX) are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-7 are currently being examined as they read upon a method for detecting a deantigenized Class I MHC T cell epitope.

3. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 60/397,758. A reference to the prior application must be inserted as the first sentence of the specification of this application if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents.

The first sentence of the specification should refer to the provisional application using language such as: This application claims the benefit of U.S. Provisional Application No. 60/____, filed ____. See MPEP 1302.04. If a statutory reference is included in this statement, if must be to 35 USC 119(e) and not to 35 USC 120.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 13 at line 29. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

6. The incorporation of *essential* material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The attempt to incorporate subject matter into the instant application by reference to foreign patents and non-patent publications may be improper because an application as filed must be complete in itself in order to comply with 35 USC 112.

An application for a patent when filed may incorporate "essential material" by reference to (1) a US patent or (2) a US patent application publication, which patent or patent publication does not itself incorporate such essential material by reference. "Essential material" is defined as that which is necessary to (1) provide a written description of the claimed invention, and the manner and process of making and using it, in such full, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention, (2) describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 USC 112, or (3) describe the structure, material or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 USC 112. In any application which is to issue as a US patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a US patent or application which itself incorporates "essential material" by reference, or (4) a foreign application. See *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the US or foreign countries or regional patent offices, (2) prior and concurrently filed, commonly owned US applications, or (3) non-patent publications. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

Applicant is invited to determine whether material incorporated by reference is essential or non-essential and amend the specification accordingly. (See MPEP 608.01(p)).

7. In Applicant's Form 1449 filed, 10/15/04, the Examiner has crossed out the titles of several references because the titles do not match the citation for the said references, but appear to correlate instead with other reference citations.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite in the recitation of "any one of the methods of claim 1" because it is not clear what is meant. Base claim 1 recites one method for detecting a deantigenized T cell epitope.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/34317 A2 (Applicant's IDS reference) as evidenced by US 20050191706 A1.

WO 00/34317 A2 teaches reducing or eliminating a potential T cell epitope peptide's ability to bind to an MHC molecule, said MHC molecule being a class I molecule. WO 00/34317 A2 further teaches reducing or eliminating the immune response to said protein whereby one or more MHC binding peptides which are also found in the autologous organism's endogenous proteins are modified to reduce or eliminate binding to MHC molecules, while making certain that the original biological activity of the altered protein is retained. WO 00/34317 A2 teaches that the method comprises determining the amino acid sequence of the protein or the part thereof that is to be modified, identifying potential T cell epitopes within the amino acid sequence of the protein by any method including determination of the binding of peptide/MHC complexes to TCRs or T cells or analyzing the primary sequence of a protein for the presence of MHC class I binding motifs, then altering the protein or portion thereof to remove one or more of the potential T cell epitopes by alteration of one or more amino acid residues within the MHC binding peptides so that they have reduced binding or no binding at all to an MHC molecule (especially page 4 at lines 11-26, page 7 at lines 4-19, paragraph spanning pages 8-9, page 10 at lines 11-30, page 11, page 12 at lines 1-12, claims 1, 4, 14 and 15).

Evidentiary reference US 20050191706 A1 discloses that the typical dissociation constant between a peptide antigen and an MHC molecule ranges from micromolar to nanomolar ([0030]).

Although WO 00/34317 A2 does not explicitly teach that the deantigenized T cell epitope identified by the art method possesses the property of having a dissociation constant with the soluble MHC molecule greater than or equal to about 5×10^{-7} (about 500nM), about 5×10^{-5} (about 50uM), or about 5×10^{-3} (about 5 mM), the art method appears to produce a deantigenized T cell epitope having said dissociation constant as evidenced by US 20050191706 A1.

The art method identifies an altered class I MHC T cell epitope that has reduced or no binding to MHC class I.

The Examiner notes that there is no recitation of a method step in the instant claims to test or produce a deantigenized T cell epitope having the said dissociation constant, the identified deantigenized T cell epitope merely possesses the property of having the recited dissociation constant.

Claim 2 is included in this rejection because the art reference teaches providing one or more altered T cell epitopes that are different. *The Examiner notes that the claim language does not recite that the deantigenized T cell epitope is improved upon by further altering its sequence.*

Therefore, the claimed process appears to be the same as the process of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the process of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the process of the instant invention and that of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/34317 A2 (Applicant's IDS reference) and further in view of US 20050063983 A1.

WO 00/34317 A2 teaches reducing or eliminating a potential T cell epitope peptide's ability to bind to an MHC molecule, said MHC molecule being a class I molecule. WO 00/34317 A2 further teaches reducing or eliminating the immune response to said protein whereby one or more MHC binding peptides which are also found in the autologous organism's endogenous proteins are modified to reduce or eliminate binding to MHC molecules, while making certain that the original biological activity of the altered protein is retained. WO 00/34317 A2 teaches that the method comprises determining the amino acid sequence of the protein or the part thereof that is to be modified, identifying potential T cell epitopes within the amino acid sequence of the protein by any method including determination of the binding of peptide/MHC complexes to TCRs or T cells or analyzing the primary sequence of a protein for the presence of MHC class I binding motifs, then altering the protein or portion thereof to remove one or more of the potential T cell epitopes by alteration of one or more amino acid residues within the MHC binding peptides so that they may have reduced binding or no binding at all to an MHC molecule (especially page 4 at lines 11-26, page 7 at lines 4-19, paragraph spanning pages 8-9, page 10 at lines 11-30, page 11, page 12 at lines 1-12, claims 1, 4, 14 and 15).

WO 00/34317 A2 *does not teach a step* to detect one or more altered T cell epitopes possessing a dissociation constant that is recited in instant claims 3-5, nor does it teach further altering an identified deantigenized T cell epitope.

US 20050063983 A1 discloses that for a peptide epitope to be useful for binding to an MHC class I molecule, it has a dissociation constant of binding of less than about 500 nM ([0055] and claim 1).

It would have been prima facie obvious to one of ordinary skill at the time the invention was made to have selected a peptide having a dissociation constant higher than the value disclosed to be useful for peptide binding to MHC class I by U.S. 2050063983 A1, *i.e.,* a dissociation constant greater than 500 nM recited in instant claim 5, and including those constants recited in instant claims 3 and 4.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to produce a deantigenized T cell epitope such as taught by WO 00/34317 A2 that does not possess stable binding to an MHC class I molecule and would therefore not be useful for eliciting a T cell response because US 20050063983 A1 discloses that useful peptide binding to MHC class I occurs with a dissociation constant of 500 nM.

14. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119492 A1 and further in view of DiBrino *et al* (J. Immunol. 1993, 151(11): 5930-5935) and US 20050063983 A1.

US 2002/0119492 A1 discloses a method for generating a modified polypeptide that exhibits reduced immunogenicity wherein a T cell epitope(s) is identified that binds to a class I MHC molecule, said method including computational methods or physical methods such as high affinity binding assays, the epitope(s) is altered to reduce or eliminate binding to said class I MHC molecule, and the modified polypeptide is tested to insure that its activity is similar to its activity before it was modified (especially abstract, [0016], [0029], [0032], [0039], [0040], [0123]-[0127] [0132], [0135], [0139], [0142], [0146]-[0148], claims).

US 2002/0119492 A1 does not disclose wherein the altered T cell epitope is evaluated by contacting the altered T cell epitope with a soluble MHC class I molecule for sufficient time to permit MHC-epitope binding complexes to form, *nor does it disclose a step* to measure the dissociation constant of the said altered T cell epitope.

DiBrino *et al* teach that the presence of anchor residues is not sufficient for binding to a class I MHC molecule, some amino acid residues other than the most favorable anchor residues can be accommodated for peptide binding, and amino acid residues at other positions may be important for binding (especially last two paragraphs of article). DiBrino *et al* further teach a peptide binding assay using soluble MHC class I molecules that measures the stability of HLA complexes by measuring the rate of dissociation of iodinated β2m at 37 degrees C (especially materials and methods section at column 2, paragraph 1).

US 20050063983 A1 discloses that for a peptide epitope to be useful for binding to an MHC class I molecule, it has a dissociation constant of binding of less than about 500 nM (especially [0055] and claim 1).

It would have been prima facie obvious to one of ordinary skill at the time the invention was made to have identified potential T cell epitope peptide(s) in a polypeptide as disclosed by US 2002/0119492 A1, to have tested the peptide(s) for reduced or no ability to bind to a selected MHC class I molecule using an assay as taught by DiBrino *et al*, to have selected a peptide(s) having a dissociation constant higher than the value disclosed to be useful for peptide binding to MHC class I by US 2050063983 A1, *i.e.*, a dissociation constant greater than 500 nM recited in instant claim 5 and including those constants recited in instant claims 3 and 4, and to have constructed an altered less immunogenic polypeptide with similar biological activity to the unaltered polypeptide as disclosed by US 2002/0119492 A1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to produce a deantigenized T cell epitope(s) and protein containing said epitope(s) such as taught by US 2002/0119492 A1, said epitope does not possess stable binding to an MHC class I molecule and would therefore not be useful for eliciting a T cell response because US 20050063983 A1 discloses that useful peptide binding to MHC class I occurs with a dissociation constant less than 500 nM, and DiBrino *et al* teach that the presence, or by extension, absence of anchor residues does not always correlate with peptide binding or altered binding when potential MHC class I binding peptides are identified on the basis of their anchor amino acid residues, and DiBrino *et al* teach an assay for measuring the binding of said peptides to a selected soluble MHC class I molecule.

Claim 2 is included in this rejection because the art reference teaches providing one or more altered T cell epitopes that are different. *The Examiner notes that the claim language does not recite that the deantigenized T cell epitope is improved upon by further altering its sequence.*

15. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119492 A1 and further in view of DiBrino *et al* (J. Immunol. 1993, 151(11): 5930-5935).

US 2002/0119492 A1 discloses a method for generating a modified polypeptide that exhibits reduced immunogenicity wherein a T cell epitope(s) is identified that binds to a class I MHC molecule, said method including computational methods or physical methods such as high affinity binding assays, the epitope(s) is altered to reduce or eliminate binding to said class I MHC molecule, and the modified polypeptide is tested to insure that its activity is similar to its activity before it was modified (especially abstract, [0016], [0029], [0032], [0039], [0040], [0123]-[0127] [0132], [0135], [0139], [0142], [0146]-[0148], claims).

US 2002/0119492 A1 does not disclose wherein the altered T cell epitope is evaluated by contacting the altered T cell epitope with a soluble MHC class I molecule for sufficient time to permit MHC-epitope binding complexes to form.

DiBrino *et al* teach that the presence of anchor residues is not sufficient for binding to a class I MHC molecule, some amino acid residues other than the most favorable anchor residues can be accommodated for peptide binding, and amino acid residues at other positions may be important for binding (especially last two paragraphs of article). DiBrino *et al* further teach a peptide binding assay using soluble MHC class I molecules that measures the stability of HLA complexes by measuring the rate of dissociation of iodinated β2m at 37 degrees C (especially materials and methods section at column 2, paragraph 1).

It would have been prima facie obvious to one of ordinary skill at the time the invention was made to have identified potential T cell epitope peptide(s) in a polypeptide as disclosed by US 2002/0119492 A1, to have tested the peptide(s) for reduced or no ability to bind to a selected MHC class I molecule using an assay as taught by DiBrino *et al*, and to have constructed an altered less immunogenic polypeptide with similar biological activity to the unaltered polypeptide as disclosed by US 2002/0119492 A1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to produce a deantigenized T cell epitope(s) and altered polypeptide containing said epitope(s) such as taught by US 2002/0119492 A1 that does not possess stable binding to an MHC class I molecule and would therefore not be useful for eliciting a T cell response because DiBrino *et al* teach that the presence, or by extension, absence of anchor residues does not always correlate with peptide binding or altered binding when potential MHC class I binding peptides are identified on the basis of their anchor amino acid residues, and DiBrino *et al* teach an assay for measuring the binding of said peptides to a selected soluble MHC class I molecule.

Claim 2 is included in this rejection because the art reference teaches providing one or more altered T cell epitopes that are different. *The Examiner notes that the claim language does not recite that the deantigenized T cell epitope is improved upon by further altering its sequence.*

The Examiner notes that there is no recitation of a method step in the instant claims to test or produce a deantigenized T cell epitope having the said dissociation constant, the identified deantigenized T cell epitope merely possesses the property of having the recited dissociation constant. In addition it is an expected property of a T cell epitope that is altered to eliminate its ability to bind MHC class I that it would possess a dissociation a dissociation constant greater than 500 nM recited in instant claim 5, and including those constants recited in instant claims 3 and 4.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 28, 2006

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